Exhibit 300: Capital Asset Summary

Part I: Summary Information And Justification (All Capital Assets)

Section A: Overview & Summary Information

Date Investment First Submitted: 2009-06-30
Date of Last Change to Activities: 2011-09-28
Investment Auto Submission Date: 2012-02-24
Date of Last Investment Detail Update: 2011-10-31
Date of Last Exhibit 300A Update: 2012-07-23
Date of Last Revision: 2012-04-26

Agency: 009 - Department of Health and Human Services **Bureau:** 25 - National Institutes of Health

Investment Part Code: 01

Investment Category: 00 - Agency Investments

1. Name of this Investment: NIH NCI Cancer Therapy Evaluation Program (CTEP)

2. Unique Investment Identifier (UII): 009-000000833

Section B: Investment Detail

1. **Provide a brief summary of the investment, including a brief description of the related benefit to the mission delivery and management support areas, and the primary beneficiary(ies) of the investment. Include an explanation of any dependencies between this investment and other investments.**

The Cancer Therapy Evaluation Program Enterprise System (CTEP-ESYS) project is the primary data collection mechanism for NCI's vast clinical trials program. CTEP-ESYS collects safety and clinical results data on 1,356 ongoing cancer clinical trials (trials not yet completed) that monitor more than 27,500 patients per year in more than 24 disease areas. Data reporting and analysis in real time is critical to ensuring adequate monitoring of the ongoing clinical research. Timely data reporting and analysis also assures effective planning for the required successor studies, thus accelerating the evaluation of promising new agents and regimens for patients with cancer. An effective CTEP-ESYS allows investigators and researchers to focus on scientific opportunity, patient safety and reducing the burden of cancer on the public by finding better ways to treat, control and cure cancer. There are more than 22 integrated components that support CTEP needs including protocol tracking, drug authorization and tracking, clinical data reporting, adverse event reporting and processing, clinical trials auditing, financial management, IND and disease management and tracking, annual report generation, regulatory activities, account management, investigator registration, reporting and analysis, and more. CTEP-ESYS is an integrated flexible modular user-friendly IT system that supports the cancer-clinical trials infrastructure. CTEP-ESYS includes an effective and well-constructed management tool that mines complex drug, disease and clinical data into meaningful information and knowledge for decision-making. The goals of

CTEP-ESYS are to: - Provide reliable clinical results and toxicity data for the largest sponsor of cancer clinical trials in the U.S. - Shift focus from administrative tasks to science - Improve patient/trial safety - Assure the security and confidentially of proprietary and patient information - Eliminate data redundancy throughout the oncology community - Empower staff to make educated decisions by improving access, quality and timeliness of data - Enhance staff efficiency and capabilities - Provide a Cost Effective Approach to Addressing Administrative, Scientific and Regulatory Concerns.

2. **How does this investment close in part or in whole any identified performance gap in support of the mission delivery and management support areas? Include an assessment of the program impact if this investment isn't fully funded.**

NCI still has a business need for CTEP-ESYS. It supports the NCI mission. No legislation, administration direction, or HHS goal or priority has minimized the need for CTEP-ESYS. Also, CTEP-ESYS directly supports the Federal Transition Framework (FTF) Goal for Federal Health Architecture by improving management of the data collected by using information technology. CTEP-ESYS should not be eliminated.

3. **Provide a list of this investment's accomplishments in the prior year (PY), including projects or useful components/project segments completed, new functionality added, or operational efficiency achieved.**

Federal IT Dashboard ranking– CTEP-ESYS, being a major investment, is tracked on the Federal IT Dashboard. During the January 2011 evaluation it scored 9.8 out of 10 and was ranked #1 amongst all NIH investments, and #4 amongst all DHHS investments. Timeline: December 2010 OEWG/Secure Website is a collaborative site available to NCI/CTEP and external stakeholders participating on clinical trials sponsored by NCI/CTEP. The site is intended to provide access to OEWG (Operational Efficiency working Group) timeline reports for protocols for tracking and monitoring the development progress of cancer clinical trials that is of interest. It enables the collaborators to manage and track the trials better in order to improve the lives of cancer patients by finding better ways to treat, control and cure cancer. Timeline: Version 1 July 2010.

4. **Provide a list of planned accomplishments for current year (CY) and budget year (BY).**

IPAD (Integrated Project for Agents and Diseases) is a user friendly robust data-mining tool that supports NCI personnel responsible for responding to data calls, to review and analyze accrual and demographic data and for overall better management of clinical trials portfolio. It is a comprehensive web-based search tool that enables users to query and analyze structured and unstructured data across NCI CTEP enterprise applications and various external biomedical information resources. The tool also facilitates performance monitoring through generation of customized reports, graphs and drill-down functionality. Timeline: Version 1 March 2011 Online Agent Order Processing (OAOP) facilitates the drug ordering process. It is based on based on SOA (Service Oriented Architecture) architecture and provides a web interface for Investigators and Designees and a repository for placing, shipping, and tracking drug orders. The application will increase efficiency, patient safety by increasing efficiency of drug order submission & processing. Timeline: Version 1.3 August 2011 CTMB-AIS (Clinical Trialls Monitoring Branch – Audit Information System) V3 adds the

capability for tracking Phase 1 & 2 trial audits in the CTEP-ESYS. It provides ability to CTMB to maintain information electronically and reduce paper based processes and capture all information in one single database. Timeline: Version 3.0 September 2011.

5. **Provide the date of the Charter establishing the required Integrated Program Team (IPT) for this investment. An IPT must always include, but is not limited to: a qualified fully-dedicated IT program manager, a contract specialist, an information technology specialist, a security specialist and a business process owner before OMB will approve this program investment budget. IT Program Manager, Business Process Owner and Contract Specialist must be Government Employees.**

2009-02-01

Section C: Summary of Funding (Budget Authority for Capital Assets)

1.

Table I.C.1 Summary of Funding

	PY-1 & Prior	PY 2011	CY 2012	BY 2013
Planning Costs:	$13.5	$0.4	$0.4	$0.4
DME (Excluding Planning) Costs:	$32.4	$0.9	$0.9	$0.9
DME (Including Planning) Govt. FTEs:	$0.4	$0.0	$0.0	$0.0
Sub-Total DME (Including Govt. FTE):	$46.3	$1.3	$1.3	$1.3
O & M Costs:	$33.2	$5.7	$5.9	$6.1
O & M Govt. FTEs:	$1.3	$0.2	$0.2	$0.2
Sub-Total O & M Costs (Including Govt. FTE):	$34.5	$5.9	$6.1	$6.3
Total Cost (Including Govt. FTE):	$80.8	$7.2	$7.4	$7.6
Total Govt. FTE costs:	$1.7	$0.2	$0.2	$0.2
# of FTE rep by costs:	16	1	1	1
Total change from prior year final President's Budget ($)		$0.2	$0.2	
Total change from prior year final President's Budget (%)		2.26%	2.27%	

2. If the funding levels have changed from the FY 2012 President's Budget request for PY or CY, briefly explain those changes:

We modified our FTE cost to be more accurate.

Section D: Acquisition/Contract Strategy (All Capital Assets)

Table I.D.1 Contracts and Acquisition Strategy

Contract Type	EVM Required	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	IDV Agency ID	Solicitation ID	Ultimate Contract Value ($M)	Type	PBSA ?	Effective Date	Actual or Expected End Date
Awarded	0261	HHSN261200900008C	No	hhsn							

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:
Earned value is required by this contract. EVM is reported on a monthly basis and we use it to monitor cost and schedule of the investment.

Exhibit 300B: Performance Measurement Report

Section A: General Information

Date of Last Change to Activities: 2011-09-28

Section B: Project Execution Data

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
298092	CTEP ESYS	The Cancer Therapy Evaluation Program Enterprise System (CTEP-ESYS) is the primary data collection mechanism for the Division of Cancer Treatment and Diagnosis' vast clinical trials program. CTEP-ESYS collects safety and clinical results data on 1,356 ongoing cancer clinical trials (trials not yet completed); of those 1,116 are treatment trials. CTEP-ESYS tracks more than 27,000 patients per year in more than 24 disease areas. The system supports 517,000 drug orders and 37,000 registered investigators. Data reporting and analysis in real time is critical to ensuring adequate monitoring of the ongoing clinical research. Timely data reporting and analysis also assures effective planning for the required successor studies, thus accelerating the evaluation of promising new agents and regimens for patients with cancer.			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		An effective CTEP-ESYS allows investigators and researchers to focus on scientific opportunity, patient safety and reducing the burden of cancer on the public by finding better ways to treat, control and cure cancer. There are many components that support CTEP needs including protocol tracking, agent authorization and tracking, clinical data reporting, adverse event reporting and processing, clinical trials auditing, financial management, investigational new agent and development, disease management and tracking, annual report generation, regulatory activities, account management, investigator registration, reporting and analysis. CTEP-ESYS consist of a common repository that interfaces with suite of applications that are integrated and support the cancer-clinical trials infrastructure.			

Activity Summary

Roll-up of Information Provided in Lowest Level Child Activities

Project ID	Name	Total Cost of Project Activities ($M)	End Point Schedule Variance (in days)	End Point Schedule Variance (%)	Cost Variance ($M)	Cost Variance (%)	Total Planned Cost ($M)	Count of Activities
298092	CTEP ESYS							

Key Deliverables

Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)

Key Deliverables

Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
NONE								

Section C: Operational Data

Table II.C.1 Performance Metrics

Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency
Amount of time it takes to abstract a protocol into the Protocol Authorization and Tracking System (PATS)	hours	Customer Results - Timeliness and Responsiveness	Under target	48.000000	36.000000		32.000000	Semi-Annual
Amount of time it takes to submit annual reports to the Food and Drug Administration (FDA)	days	Customer Results - Timeliness and Responsiveness	Under target	30.000000	25.000000		20.000000	Monthly
Number of active principal investigators (PI) registered by CTEP	number	Process and Activities - Productivity	Over target	14886.000000	15000.000000		15250.000000	Monthly
Mean number of days to approve a protocol from receipt of concept or letter of intent (LOI) through the use of the Document Authoring, Review, and Tracking system (Docu-MART)	number	Technology - Effectiveness	Over target	367.000000	350.000000		345.000000	Semi-Annual
Track the increase in the amount of patients in the CDUS	number	Technology - Efficiency	Over target	870091.000000	870150.000000		870165.000000	Quarterly